Site visit inspection report on compliance with HTA minimum standards

BioHorizons UK

HTA licensing number 11008

Licensed for the

- **import, storage, distribution and export of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

30-31 May 2018

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that BioHorizons UK (the establishment) had met the majority of the HTA standards, five minor shortfalls were found in relation to the Governance and Quality Systems (GQS) standards. The five minor shortfalls were in relation to the requirement for the establishment to ensure imports from the USA meet the standards of quality and safety as set out in Directions 002/2018, the format of the Single European Code (SEC) as applied by the establishment to their products, the establishment's contingency agreements in the event of termination of activities, the access staff have to risk assessments and the temperature recording of the room where tissue and cell (T&C) products are stored.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as ‘Critical’, ‘Major’ or ‘Minor’ (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA’s website.

Licensable activities carried out by the establishment

Tissue category; Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Membrane, Pericardium				**E***	**E***	**E***	**E***
Musculoskeletal, Bone; Acellular Bone				**E**	**E**	**E**	**E***
Musculoskeletal, Bone; Cancellous Bone Particles				**E**	**E**	**E**	**E***
Musculoskeletal, Bone; Demineralised Bone Matrix (DBM)				**E**	**E**	**E**	**E***
Musculoskeletal, Bone; DBM Putty				**E**	**E**	**E**	**E***
Skin				**E**	**E**	**E**	**E***

'E' = Establishment is licensed to carry out this activity.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

Background to the establishment and description of inspection activities undertaken

BioHorizons UK (the establishment) is licensed for the import, storage, distribution and export of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). The establishment imports acellular bone products (chips and putty), skin products and is also licensed to import pericardium; the latter activity is currently not carried out. The establishment is located at Bracknell, Berkshire.

BioHorizons Implant Systems Incorporated (Inc.), based in the USA, is the parent company and the third country supplier (3CS) of products to the establishment. All the material is procured from deceased donors and processed in four tissue banks also based in the USA. The four tissue banks are subcontracted to carry out this work by the parent company. The 3CS and four SCs are regulated by the FDA. All the subcontractors (SCs) are also American Association of Tissue Banks (AATB)-accredited. The four SCs undertake the processing of the T&C products and oversee the mandatory serology testing for infectious diseases of all the donors. The tests themselves are carried out under agreement with CLIA-accredited

public laboratories. BioHorizons UK imports the T&C products directly from the parent company in the USA.

The staff at the establishment undertake visual checks of the packaging and ensure that the quantity, single European code (SEC) and lot numbers of the products match those on their receipt list. Once these checks have been conducted the products are added to the inventory list, ready for distribution. On a daily basis the head office in the USA provides the establishment a daily list of products in stock including products nearing expiry. For any expired T&C products deemed suitable for disposal, a member of the establishment's staff first obtains the appropriate manufacturer's return authorisation number, before the products are sent directly back to the SCs to be disposed of.

The parent company allocates the SEC and BioHorizons UK applies it to the T&C products upon arrival (*see Advice item, 1*). The SEC contains the batch ID number, within the donation identification sequence (DIS), provided by the SCs. For acellular products, each batch number can be traced back to the same donor, but each item does not have a unique individual serial number or split number.

All aspects of ordering, receipt, storage, disposal, and distribution to end users of the T&C products is recorded on both paper-based records, stored securely within the facility, and on an electronic database system shared with the parent company. The latter is backed-up regularly.

The establishment has been licensed by the HTA since October 2008. This routine inspection was the establishment's fifth inspection since the establishment was licensed and the first since Directives 2015/565 and 2015/566 were transposed into UK law on 1 April 2018. The inspection included interviews with the DI and other key members of staff including the US Director of Regulatory Affairs. A review of documentation, including the processing records of three imported products selected prior to the inspection and already distributed to end users, and an audit of traceability of a skin and two acellular bone products in storage was also undertaken.

The processing records were reviewed for evidence of appropriate serology and sterility testing, release forms and the results of environmental monitoring or terminal sterilisation. There were a number of discrepancies noted in relation to the format of the SEC and the environmental monitoring for T&C products that did not undergo terminal sterilisation (*see shortfalls against standards GQ1(n) and GQ6(a)).*

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.	At the time of the inspection there was no contingency plan with provisions for termination of activities including the transfer of stored T&C products to another licensed establishment (or transfer to Head Office). *Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the above shortfall.*	**Minor** *The HTA has assessed this information as satisfactory and considers this standard to be met.*
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 002/2018.	At the time of the inspection two of the third country supplier's subcontractors did not meet the requisite air particle requirements for measurements at rest and in operation as set out in Directions 002/18.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.	The establishment does not have a documented contingency plan that will ensure that in the event of termination of activities raw data and records of traceability will be maintained for the requisite 10 and 30 years respectively. *Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the above shortfall.*	**Minor** *The HTA has assessed this information as satisfactory and considers this standard to be met.*

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The establishment applies the SEC provided by BioHorizons Inc. However, the format of the SEC is not in line with requirements. For example, the establishment does not include a split number for acellular products originating from a single donation event.	**Minor**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.	The manufacturers of the T&C products recommend a temperature range of 1528˚C, where the products are stored. Establishment staff monitor and document the temperature during working hours on Monday to Friday only. There is no provision for reviewing and recording temperatures over the weekend and bank holidays and as a result, there is a risk that any deviations that take place over the weekend may go unnoticed. Furthermore, a review of the temperature records indicated an occasion, where temperatures over 28˚C were recorded. This deviation was not recorded as a nonconformance as per the establishment's procedures and appropriate action was not taken to establish what impact, if any, this excursion had on the quality and safety of the product. *Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the above shortfall.*	**Minor** *The HTA has assessed this information as satisfactory and considers this standard to be met.*

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1 (b)	The DI is advised to update the establishment's procedures to reflect the fact that the parent company allocates the SEC which is then applied by the establishment upon receipt of the T&C products.
2.	GQ2(b)	The DI is advised to review the establishment's approach to the audit of records. Consideration should be given to expanding the scope of such audits to include training records and temperature charts, some of which were found to be incomplete during the inspection.
3.	GQ2(c)	The DI is advised to review the audit template used to carry out the independent audit and include the content of what was audited against each applicable HTA standard. The DI is advised to expand the scope of the audits of the SCs to also include horizontal audits of batch processing records for each of the tissue types imported by the establishment. This will help ensure that the products supplied by the SCs and 3CS meet the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).
4.	GQ8 (a)	The DI is advised to review the format of the establishment's risk assessments and to consider the use of risk matrices. As part of this review, the DI is advised to ensure that the full range of existing control measures are documented. The DI is also advised to consider the way risk assessments are used as part of staff induction and training.

Concluding comments

The HTA saw various examples of good practice during the inspection.

There is a good working relationship and a comprehensive and effective system of communication between the establishment and the parent company, including biannual meetings. The establishment has a robust system in place for managing documentation including operating procedures, complaints and non-conformances. These are mostly centrally managed by the parent company; however, document review of local documents involves three levels of checks including a member of staff from the establishment, followed

by the DI and a Quality Assurance Engineer in the USA. Establishment staff take a photocopy of the SEC and the lot number, before the distribution of T&C products to end users. An electronic copy is sent to the 3CS in the USA to be stored and a physical copy of the traceability numbers is retained with the invoice and stored at the establishment. The US establishment assures itself as part of its audits of the SCs that there are procedures in place for ensuring the dignity of deceased donors and that reconstruction of bodies following recovery of the tissues and cells is carried out respectfully. The US Director of Regulatory Affairs has a detailed audit checklist for each of the four SCs and physically inspects them on an annual basis.

Five areas of practice were identified during the inspection that require improvement, each resulting in minor shortfalls. The HTA has given advice to the Designated Individual to update a procedure to include the application of the SEC, the risk assessments, the independent audit and the audit of the SCs.

The HTA requires that the Designated Individual addresses the minor shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 2018/07/06

Report returned from DI: 2018/07/20

Final report issued: 2018/07/27

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 2020/05/20

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.

d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.

g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 002/2018.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.

c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.

d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.

e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.

c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard

PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 002/2018.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.

e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
D2 The reasons for disposal and the methods used are carefully documented.

a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

Or

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

Or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient *or*

A shortfall in the establishment's quality and safety procedures which poses an indirect risk

to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions; *or*

A shortfall which indicates a breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines; *or*

A shortfall which indicates a failure to carry out satisfactory procedures or a failure on the part of the designated individual to fulfil his or her legal duties; *or*

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.